

The principles that guide the development of NICE guidance and standards

Introduction

1. Since NICE was established in 1999, we have developed and gradually refined a series of public statements about how we develop our guidance and standards. These documents include our [methods and process guides](#), a separate statement of our approach to making [social value judgements](#), and the work of our [Citizens Council](#). Together, they guide the work of our independent advisory groups and help those involved and interested in NICE understand how we work. All these documents have helped inform a set of principles on which we base our approach to our work.
2. As our programmes have developed and new responsibilities have been added, we have had to keep these principles up to date. Until now, we used the statement of our approach to making social value judgments to do this. This was last updated in 2008. Although much of what it contains is still relevant to our work, we consider that it is no longer the best way to communicate the principles. This is partly because what it contained has been absorbed into our methods and process manuals, where it is more helpfully contextualised. And it is partly because what was once new and unfamiliar about how NICE works is now, after almost 2 decades, well understood and accepted. This includes concepts such as transparency, engagement and contestability.
3. Nevertheless, it remains important that we are able to set out, clearly and simply, why and how we work in the way that we do. In this document, we set out the principles that guide the development of NICE guidance and standards. It links to and is consistent with the legislation that establishes NICE in its current form, the NICE charter, and other legal, ethical and technical considerations that relate to decisions about how to allocate fixed resources in health and social care.
4. We hope this document will be of interest to anyone involved in developing NICE's guidance and standards and to anyone else who would like to know more about how NICE goes about its work.

The principles

Principle 1. Prepare guidance and standards on topics that reflect national priorities for the population's health and care

5. NICE's remit covers health, public health and social care, as set out in the [Health and Social Care Act 2012](#). To ensure our guidance and standards appropriately cover this breadth of topics, we operate a number of different prioritisation processes.
6. We welcome topic suggestions from a range of sources, including people using services, health professionals, manufacturers and commercial sponsors, and the National Institute for Health Research (NIHR) horizon scanning function. We select and prioritise topics in collaboration with our partners in the Department of Health and Social Care, Public Health England and NHS England, to ensure our topics reflect the ambitions and capacity of the health and care system. We do this using criteria that include prevalence of the disease or condition, variation in care, and the available evidence.

Principle 2. Use evidence that is relevant, reliable and robust

7. NICE guidance and standards are underpinned by evidence, so we need to ensure that the evidence we use is relevant, reliable and robust. To do this, we have a range of processes for identifying research evidence, for assessing its quality, and for determining whether it is relevant to the question under consideration.
8. For each guidance-related question, we consider the appropriateness of research methodology used to produce the evidence. We take a comprehensive approach to assessing evidence, and don't focus on traditional 'hierarchies of evidence' alone. Our process and methods manuals set out the types of evidence that are generally appropriate for different types of question. This can include evidence derived from qualitative and quantitative methodology from the literature or submitted by stakeholders, as well as real world data and evidence from expert and public testimonies.
9. NICE aims to support innovation in the provision and organisation of health and social care services, by encouraging interventions that are good value for money and have plausible potential to substantially improve outcomes for patients. The importance of promoting innovation in the provision of health services and social care is also set out in the [Health and Social Care Act 2012](#).

Principle 3. Set out frameworks for interpreting the evidence in our process and methods manuals, and review them regularly

10. NICE's guidance can have a significant impact on health and care services, and on individual people's lives, so it is important that we are explicit about the approaches we use and allow others to comment on them. The [NICE \(Constitution and Functions\) Regulations 2013](#) also require us to have, and consult on, procedures for giving advice or guidance, and making recommendations. The principles of the [NHS Constitution](#) also highlight the importance of transparency and accountability in our decision-making processes.
11. All our guidance and standards programmes therefore have detailed process and methods manuals that go through rigorous review, assessment and consultation before being published, and are updated regularly. We are required to follow our documented processes and methods and are therefore accountable for the decisions that we make. There may be occasions when it is appropriate for us to depart from the documented processes and methods for particular recommendations. When this happens, we clearly explain our rationale in the documentation.

Principle 4. Use independent advisory committees to develop recommendations

12. To ensure that our recommendations are unbiased, objective and truly evidence-based, we use independent advisory committees to consider the evidence. Even the best, high quality research evidence will never be complete and comprehensive, so its consideration by a committee independent of NICE is essential.
13. Committees include people from the NHS and social care services, academia, relevant industries, patient-carer organisations and the general public. All committee members declare any relevant interests both annually and for each committee meeting they attend.

Principle 5. Take into account the advice and experience of people using services, health and social care professionals, commissioners and providers

14. NICE needs to ensure that the process for developing guidance and standards involves people who will be affected by the recommendations, to ensure their needs and priorities are reflected. We build in these perspectives through the membership of our guidance development committees or, when this isn't possible, by providing expert testimony to the committee.
15. Committee members are selected for their knowledge and experience. They are each there in their own right and do not represent organisations they work in. Lay members reflect the experiences of a wide range of people affected by the

guideline rather than basing their views solely on personal experience. Organisations that represent patients, service users, carers and the wider public, alongside health professionals and others, are also involved in defining the scope of our products, and invited to submit evidence for the committee to consider.

Principle 6. Base our recommendations on an assessment of population benefits and value for money

16. When NICE was established, the directions from the Secretary of State for Health made clear that we are to take into account both the costs and benefits of interventions referred to in our recommendations, and encourage the effective use of resources. The importance of this was restated in the [Health and Social Care Act 2012](#), which requires us to have regard to the broad balance between the benefits and costs of the provision of health services or of social care in England. We must also take account of our commitment under the [NHS Constitution](#) to provide “the best value for taxpayers’ money and the most effective, fair and sustainable use of finite resources”.
17. The way that we assess value for money is set out in detail in our method manuals. The approach takes into account the ‘opportunity cost’ of recommending something new, highlighting that there would have been other potential uses of the resource. It considers the needs of other people using services (both now and in the future) who are not known and not represented in the decision. Therefore the primary consideration underpinning our guidance and standards is the overall population need.
18. For treatments that extend life for people at the end of life, and for highly specialised technologies where specific criteria are satisfied, we may recommend an intervention with a cost-effectiveness estimate above our normally acceptable range.

Principle 7. Give people interested in the topic area the opportunity to comment on and influence our recommendations

19. NICE recommendations are based on complex considerations of the evidence by our committees, and it is important that a wider group of stakeholders also have the opportunity to comment. This wider consultation helps ensure the validity of the final recommendations. The principles of the [NHS Constitution](#) also require us to be accountable to the public, communities and patients that we serve, and to make decisions in a clear and transparent way.
20. All our guidance and standards are therefore developed using a process that takes into account the opinions and views of the people who will be affected by it. We consult openly with organisations that represent people using services, carers and the wider public as well as health and social care professionals, NHS organisations, industry, social care businesses and local government. Our

advisory committees consider and respond objectively to comments and, where appropriate, amend the recommendations.

Principle 8. Lead work with partners in the health and care system to encourage and support the adoption of our recommendations

21. NICE guidance and standards will not have any impact if they are not used by the health and care system. When implemented effectively, NICE resources can support local improvement initiatives, improve outcomes and reduce variations in practice across the country.
22. Our [implementation strategy](#) supports adoption of our recommendations through producing guidance and standards that are fit for the audience's needs, by ensuring relevant audiences know about our recommendations, motivating and encouraging improvement, highlighting practical support to improve local capability and opportunity, and evaluating impact and uptake. We actively work with strategic partners to reinforce NICE recommendations in all relevant national and regional initiatives.

Principle 9. Assess the need to update our publications in line with new evidence

23. NICE guidance and standards need to be up-to-date to ensure patients receive up-to-date care and advice, and to be credible for professional groups. The [NICE \(Constitution and Functions\) Regulations 2013](#) also require us to review and revise, as we consider appropriate, any advice or guidance we give, information we provide or recommendations we make.
24. We regularly assess the need to update our guidance and standards. New evidence might change conclusions about the benefits and risks of an intervention, or the extent to which it represents good value for money for the health or social care system. If we find evidence that might result in a change to our recommendations, we may initiate a review of the guidance. We normally consult with relevant organisations on a proposal about whether or not guidance needs updating and, if so, how to conduct the update.

Principle 10. Propose new research questions and data collection to resolve uncertainties in the evidence

25. NICE examines the available evidence in generating guidance recommendations, and this often highlights a number of unanswered questions. Uncertainties may arise because there is no published evidence available, or the available evidence is conflicting, insufficient or not robust. If the uncertainties could affect future recommendations, we set these out as research recommendations, and liaise with the research community to ensure they are addressed.

26. We have formal processes and methods for committees to make recommendations for research. Recommendations are communicated to researchers and funders including national organisations such as the UK Research Councils and research charities, and industry. We work closely with the National Institute for Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre (NETSCC) to prioritise research recommendations.
27. Committees may also recommend the provisional use of an intervention to allow collection of more data about its effectiveness, safety or cost. This is helpful for interventions showing promise of additional benefit compared with existing alternatives, but for which the evidence for benefit is limited.

Resources

- The 2008 edition of [social value judgements: principles for the development of NICE guidance](#), which this document replaces
- The [Citizens Council reports](#)

The legislative and policy requirements that apply to NICE guidance are set out in these documents:

- [NICE \(Constitution and Functions\) Regulations 2013](#)
- [NICE charter](#)
- [NICE Patient and Public Involvement Policy](#)
- [Equality Act 2010](#)
- [Health and Social Care Act 2012](#)
- [7 principles of public life](#) (also known as the 'Nolan principles')
- [NHS Constitution](#)
- [Care Act 2014](#)
- Department of Health and Social Care's [outcomes frameworks](#)
- [Human Rights Act 1998](#)
- [Sustainable development strategy](#).